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(54) Dilator

(57) A surgical device for facilitating access to a bodily cavity comprises a tube of metal or plastic, having an internal longitudinal channel and holes extending from the channel to the outer surface of the tube. The tube is normally fitted with a sleeve of a water-swellable material, especially a hydrophilic graft copolymer. In use the tube plus sleeve is inserted into the body, percutaneously or through a bodily orifice, an aqueous medium is passed down the channel, flows through the holes, the sleeve swells and the tube may be removed, the sleeve remaining in place allowing access to the cavity. Preferably a helical groove on the outer surface of the tube links at least some of the holes.

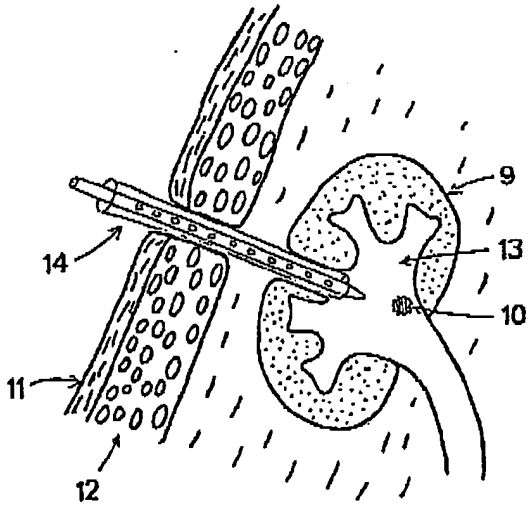

Fig.5

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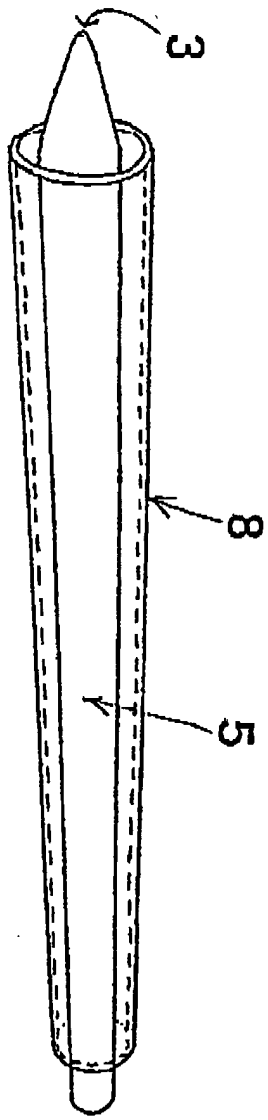

Fig.4

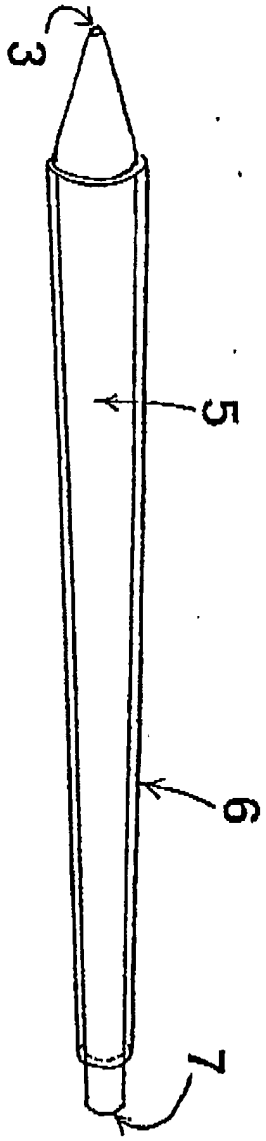

Fig.3

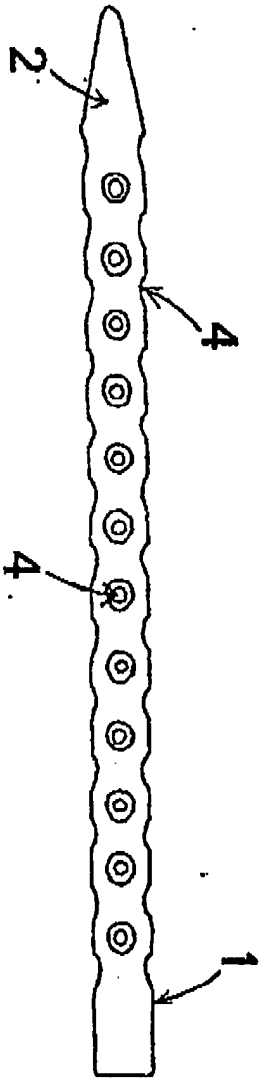

Fig.2

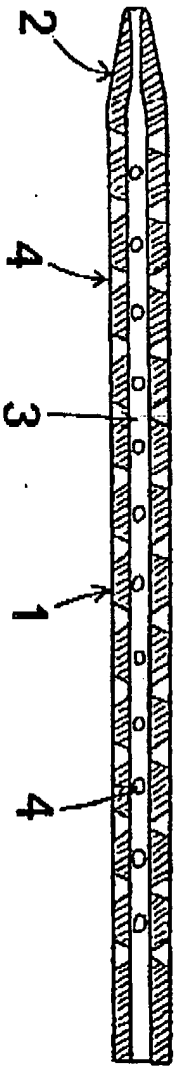

Fig.1

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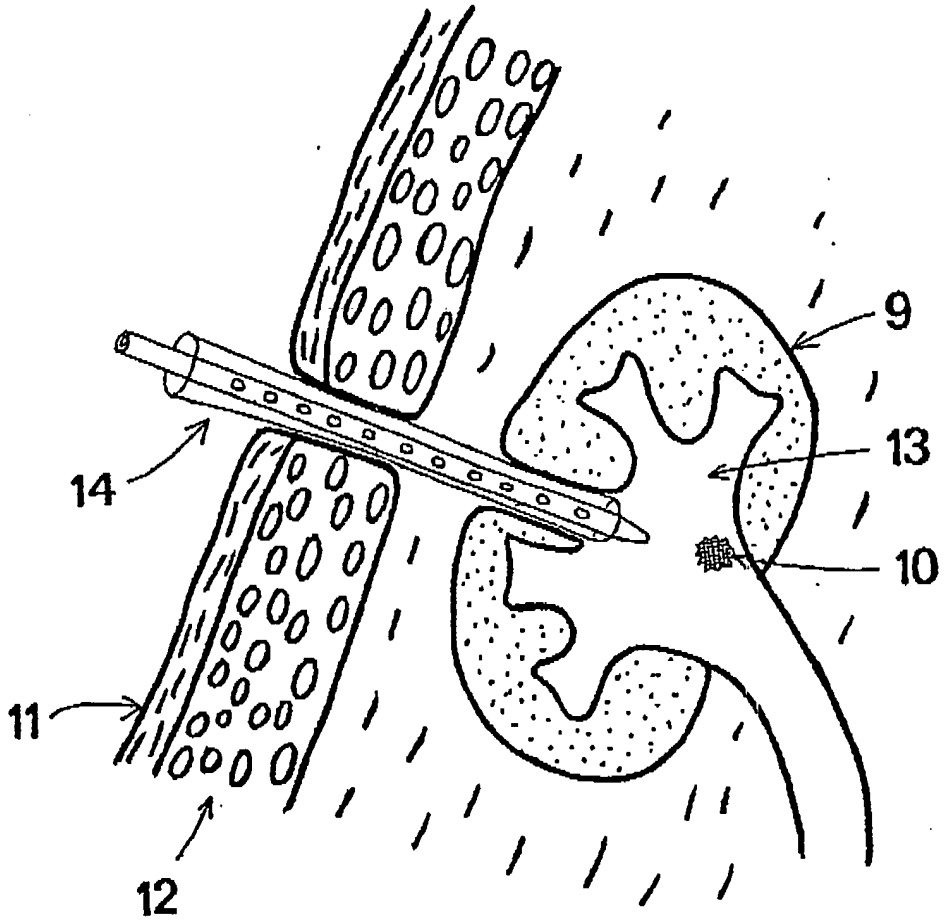

Fig.5

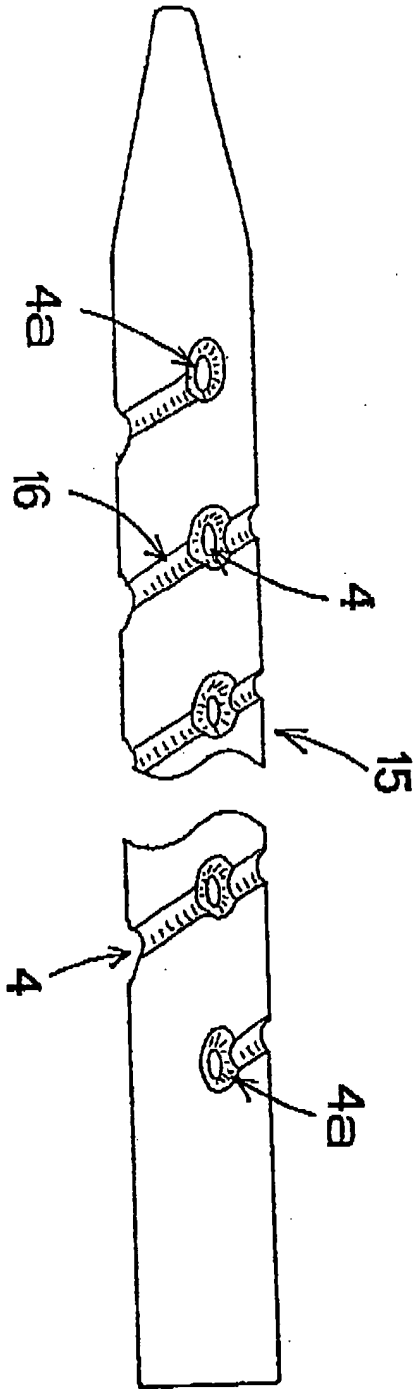

Fig. 6

SPECIFICATION

Surgical devices

This invention relates to devices for use in human or veterinary surgery. In particular the invention relates to devices for use in facilitating access to bodily cavities and spaces, especially percutaneous access.

In various fields of surgery it is necessary to provide a channel or tract from the outside of the patient's body to an internal bodily space to enable the insertion of surgical instruments or the extraction of a foreign particle such as a kidney stone whilst avoiding frictional or manipulative damage to the body wall. For example the method most widely used today to provide a percutaneous tract comprises needle puncture of the skin, of the subcutaneous tissues and of any appropriate organs, followed by insertion of a guide wire along the line of the needle, and then by the insertion of a series of concentric tubular dilators, each of greater diameter than its predecessor, so as to gradually open a channel into the patient's body. When the internal diameter of the outermost dilator constitutes a wide enough tract, the guide wire and inner dilators are removed, thus leaving the outermost dilator in place.

This method suffers from a number of disadvantages. The insertion of a number of dilators takes time. As each is normally separately sterilised and prepared, this adds to the inconvenience of the method. Considerable effort may be needed to overcome the frictional forces between the dilator and surrounding tissue, and between successive dilators. These factors all contribute to fatigue of the surgeon and trauma of the patient.

It is an object of the present invention to provide a surgical device which enables the provision of an access tract or channel to a bodily space, and which alleviates to some extent the problems of existing methods.

According to the present invention in a first aspect, a surgical device is characterised in that it comprises a tube of generally cylindrical shape and provided with an internal longitudinal channel and further provided with a plurality of holes extending from the longitudinal channel to the outer surface of the tube and further provided with a sleeve of a water - swellable material around the tube, the sleeve covering at least some of the holes.

In use in surgery to provide an access tract or channel from the outside of a patient's body to an internal bodily space the device may be used in a number of ways depending upon whether access into the patient's body is to be via a convenient bodily orifice, such as the anus, urethra, vagina, trachea or nasal passages etc., or percutaneously.

If through a bodily orifice, the tube plus sleeve may simply be inserted into the orifice. If percutaneously, eg for percutaneous nephrolithotomy, then a needle puncture is made in the patient, followed by guide wire insertion as in prior art methods. The tube plus sleeve is then threaded onto the guide wire, the wire passing through the internal channel, and is then inserted into the patient's body.

Whether insertion takes place through a bodily orifice or percutaneously, the tube plus sleeve is manipulated into the bodily space of interest. An aqueous medium is then directed along the longitudinal channel, and flows through the holes, to contact the water - swellable material. The material then expands away from the tube, and the tube may be withdrawn, leaving the expanded sleeve of water - swelled material in place as an access channel for the insertion of instruments or extraction of foreign particles. As well as expansion by contact with the aqueous medium, the water - swellable material may also be swollen by contact with bodily fluids.

The tube may be of any dimensions appropriate for the provision of an access channel to a bodily space as generally understood in the art. The tube is preferably of circular cross section but may be of elliptical section. For percutaneous renal access, for example, a tube of circular cross section, 20 cm long and 1.5 to 10 mm diameter is suitable.

For percutaneous applications, the longitudinal channel should extend for the full length of the tube and be open at both ends to enable threading onto a guide wire. For applications where the device is inserted through an existing bodily orifice the longitudinal channel need only be open at the end which is to remain outside the body to allow introduction of the aqueous media, but a device with a channel open at both ends may be used for both types of applications referred to above. The dimensions of the longitudinal channel should be adequate to enable sufficient aqueous medium to flow to expand the water swellable material in a convenient time, and in cases where the device is to be threaded onto a guide wire, of sufficient diameter to allow this. In a device for percutaneous usage for example, a channel of circular section 2.5 mm diameter in a tube 8 mm diameter was found to be entirely suitable.

The holes should be of sufficient size and number to allow a sufficient flow of the aqueous medium to the sleeve of water - swellable material to cause it to swell in a convenient time, without prejudicing the structural integrity of the tube. A preferred shape of hole is frustro-conoidal, with the narrow end inwards, so as to cause contact of as large an area of the water - swellable material as possible with the aqueous medium flowing through the holes. Other shapes of hole e.g. slits may be used, but longitudinal slits may cause a problem if the device is used in conjunction with a guide wire, as this wire may dislocate through such a slit and buckle. Preferably the holes are regularly spaced to encourage uniform swelling of the water - swellable material. In a tube 20 cm long, 8 mm diameter, with an internal longitudinal channel 2.5 mm diameter, 20 to 30 holes, 1 mm diameter at their narrow end and 3 to 4 mm diameter at their wide end, regularly spaced around and along the tube were found to be adequate.

For percutaneous applications, where the tube is threaded onto a guide wire and inserted into the patient's body through the relatively small needle puncture hole, it is preferable that the end of the tube which is to be

inserted into the patient's body is of generally conical shape, to ease entry. The term 'conical' or 'conoidal' used herein is intended to include ogivoidal shapes. A taper of the conical end of *ca* 5° to 10° is generally adequate but other tapers may be used. In the region of the conical end the internal channel may narrow. A device with a conical end may of course be used in applications where insertion is to be through a bodily orifice, where no guide wire may be necessary.

The tube may be made of any bio-tolerable, bio-compatible or inert material having adequate mechanical strength. For example metals, such as stainless steel, or plastics materials such as polyethylene, or polytetrafluoroethylene or Teflon (Trade Mark). The latter is preferred.

The flow of aqueous medium to the sleeve of water-swellable material of the device may be encouraged by providing dimples or grooves in the outer surface of the tube, in communication with at least some if not all the holes. A preferred form of groove is a helical groove.

Although tubes of the general type described above are known for use in other medical or surgical applications eg in UK Patents 1333347, 1569945 and EPA 0022370 among others, and these known tubes may in some cases be used, after any slight necessary adaptation, for the tube of the device of the present invention, the form of tube described above when provided with a helical groove or grooves is believed to be novel.

According therefore to a further aspect of the present invention there is provided a surgical device comprising a tube of generally cylindrical shape and provided with an internal longitudinal channel and further provided with a plurality of holes extending from the internal channel to the outer surface of the tube and further provided with at least one helical groove in the outer surfave of the tube in communication with at least some of the holes.

This latter surgical device may be suitable for many uses in its own right, but is principally intended for use in conjunction with the water-swellable sleeve to provide a device as described above. The other preferred aspects of the design of this latter device, ie dimensions, shape, the channel, the holes, the conical end and materials of which it is made are as described above in connection with the first device.

The water-swellable material should be bio-tolerable, bio-compatible or biologically inert. It should be strong enough to resist damage by contact with the sharp edges of surgical instruments or the jagged corners of foreign particles such as kidney stones.

A preferred form of water-swellable material is one which becomes slippery on wetting. This enables easy removal of the tube, easy insertion of surgical instruments, and easy removal of foreign particles by reducing friction. It is also then easier to remove the sleeve from the patient when the operation is over.

The extent of swelling of the water-swellable material should be such as to enable easy removal of the tube, preferably further aided by slipperiness of the wet material. Ideally the material should swell with sufficient force to dilate the surrounding tissue, but if the expansive force is insufficient, further dilation may be achieved by the insertion of a further dilator of wider diameter into the swollen sleeve, which would also be facilitated by a slippery sleeve.

The sleeve should be sufficiently tightly mounted on the tube to resist stripping when the device is inserted into the patient's body. Preferably this tightness is achieved by the use of a sleeve which contracts on drying after its expansion on wetting. In this case a sleeve of internal dimensions either the same as or preferably slightly less than the external dimensions of the tube is used. The sleeve is wetted to cause swelling, is then fitted over the tube, and allowed to dry and shrink, thus fitting the tube tightly by shrink-fitting. The sleeve should preferably cover all or substantially all of the holes when mounted on the tube.

Preferably the water-swellable material is a polymeric material. A number of these are known, for example the materials described in UK Patent 2035350, being hydrophilic graft copolymers comprising a base polymer eg polyethylene, graft copolymerised by radiation initiated graft copolymerisation with an ethylenic carboxylic acid, eg acrylic acid. Another example of such a polymermeric material is that described in PCT Application PCT/GB85/00197 (claiming priority from UK Patent Application 8412007), being an ethylene vinyl acetate copolymer similarly graft copolymerised with acrylic acid by radiation initiated graft copolymerisation and coated with polyvinyl alcohol to resist water absorption and delay swelling. The polymeric materials described in that patent and application are preferred materials, as they possess many of the desired properties discussed above, eg biotolerability, slipperiness on wetting, some 60 % swelling on wetting in some cases, contraction on drying, and adequate mechanical strength.

The aqueous medium may be any medium normally used in surgery for irrigation eg saline. The aqueous medium may be introduced into the tube by any conventional means, for example the end of the tube which is to remain outside the patient's body may be adapted to take a delivery tube leading to a bottle of the medium.

The device of the invention may be used in an alternative application for the infiltration of a percutaneous tract or a bodily orifice with a local anaesthetic, eg 1% lignocaine. In this application the tube without a sleeve is inserted into the tract or orifice, and the anaesthetic passed down the longitudinal channel to escape through the holes. Such an anaesthetic may also be used to swell a sleeve of water-swellable material in some applications.

The invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 shows a cross sectional view of a device according to the first aspect of the invention.

Figure 2 shows an orthogonal view of the device of Figure 1.

Figure 3 shows a perspective view of a device according to the second aspect of the invention before wetting of the sleeve.

Figure 4 shows the device of Figure 3 after wetting of the sleeve.

Figure 5 shows the device of the invention in use in a percutaneous lithotomy operation.

Figure 6 shows the device of the invention in the form of a tube with a helical groove.

Referring to Figures 1 and 2, a device according to the invention consists of a tube (1), being of generally cylindrical form but having one end (2) tapered into a conical shape. An internal longitudinal channel (3) extends the whole length of the tube and is open at both ends. A number of regularly spaced frustro-conoidal holes (4) pierce the walls of the tube (1), extending from the channel (3) to the outer surface of the tube (1).

Referring to Figures 3 and 4, the tube shown in Figures 1 and 2 is shown overall in perspective (5). The holes (4) are omitted from Figures 3 and 4 for clarity, but the end of the longitudinal channel (3) is shown. A sleeve (6) made of the water-swellable polymer described in PCT/GB85/00197 of dry diameter slightly less than that of the tube (5) has been wetted and allowed to expand, fitted over the tube (5), covering all the holes (4) and allowed to dry in air and shrink to fit the tube (5) tightly.

In Figure 4, water has been passed down the longitudinal channel (3) from the non-conical end (7). The water has flowed out along the holes (4), contacted the dry sleeve (6), and caused it to expand into its wet expanded form (8), simultaneously becoming slippery.

Referring to Figure 5, a kidney (9) is shown harbouring a kidney stone (10). A needle (not shown) has been inserted through the outer skin (11) and muscle (12) of the patient, into the internal space (13) of the kidney. A guide wire (not shown) has then been inserted into the kidney through the needle puncture. The tube plus sleeve of Figure 3, shown overall (14) was then threaded onto the guide wire, with its conical end toward the patient, and then inserted through the skin (11) and muscle (12) into the internal space (13) of the kidney (9). The guide wire was then withdrawn and saline was directed down the longitudinal channel (3) of the tube (14) via a plastics tube and reservoir (not shown). The sleeve (6) expanded away from the tube (1), which was then withdrawn leaving the sleeve (6) in place in its expanded slippery state, through which access to the stone (10) could be gained.

Surgical example

Four patients suffering from kidney stones were chosen. The method described above for insertion of the sleeve was used on each, using a tube of 24 ch diameter. The tube plus sleeve was inserted using X-Ray screening. The sleeve was expanded as described above using saline, and the tube was removed. A nephroscope was easily passed into the kidney of each patient. In two cases the sleeve was insufficiently strong to dilate the fascia and muscle by itself, and hence a larger Teflon (Trade Mark) dilator (32 ch) was inserted into the sleeve to force the tract open, with minimum force as the tract was now lined with the slippery sleeve.

In two cases the sleeve was able to dilate the muscle and fascia itself and the stones were extracted using alligators. A non-toothed alligator was found to be advantageous in reducing tearing of the sleeve.

Referring to Figure 6, a device according to the invention is again in the form of a tube with one generally conical end, shown overall (15), only the portion of the tube near the ends being shown, the centre portion omitted, for clarity.

The wall of the tube (15) is pierced by a number of regularly spaced frustro-conoidal holes (4). A helical groove (16) has been formed in the outer surface of the tube (15), terminating at both ends in holes (4A) and in communication with all the holes (4).

In use, a sleeve (not shown) (6) of water-swellable material is fitted over the tube (15). When an aqueous medium is made to flow down the longitudinal channel (not shown) (3) of the tube (15) eg in the course of an operation as described above, the medium flows out through the holes (4) and along the groove (16). Areas of the sleeve not covering the holes (4) are thus contacted by the aqueous medium, ie those areas covering the groove (16) and faster, more uniform swelling of the sleeve is achieved.

Water swellable sleeve

As mentioned above, the water - swellable sleeve was made of the polymer described in PCT/GB85/00197. For convenience its preparation is summarised below.

An extruded tube (nominal internal diam. 5.5 mm and wall thickness 0.3 mm) of polyethylene vinyl acetate containing 12.5 wt% vinyl acetate (supplied by ICI under code name 514) was placed in a glass vessel. The tube was then immersed in an aqueous solution of acrylic acid (25 % vol.) and $FeSO_4$ (4g / L). The vessel and contents were then evacuated by water pump for 2 hours, then pressure equalised and sealed. The vessel was then irradiated with gamma rays from a ^{60}Co source at dose rate 0.015 Mrad / hr to a total dose of 1 Mrad at 21°C. The tube was then washed with distilled water, then dried at 50°C. The tube was then immersed for 5 minutes in a 5% aqueous solution of KOH at 95°C. This was followed by a quench in distilled water at 20°C, rinsing in distilled water and drying at 50°C. Dimensional changes on subsequent water equilibration were measuresd and were as below:

	% *Change*
Length	+53
Wall thickness	+68
Internal diameter	+43
Weight	+228

CLAIMS

1. A surgical device comprising a tube of generally cylindrical shape and provided with an internal longitudinal channel and further provided with a plurality of holes extending from the internal channel to the outer surface of the tube and further provided with a sleeve of a water - swellable material around the tube, covering some if not all of the holes.

2. A surgical device as claimed in claim 1 wherein the longitudinal channel extends the full length of the tube.

3. A surgical device as claimed in claim 1 wherein the longitudinal channel is open at only one end.

4. A surgical device as claimed in any one of the preceding claims wherein the holes are frustro - conoidal in shape with their narrow end inwards.

5. A surgical device as claimed in any one of the preceding claims wherein there are dimples or grooves in the outer surface of the tube, in communication with the holes.

6. A surgical device as claimed in claim 5 wherein a helical groove is provided in the outer surface of the tube, linking some if not all the holes.

7. A surgical device as claimed in any one of the preceding claims wherein one end of the tube is of generally conical form.

8. A surgical device as claimed in any one of the preceding claims wherein the tube is made of stainless steel, polyethylene, polytetrafluoroethylene or Teflon (Trade Mark).

9. A surgical device as claimed in any one of the preceding claims wherein the water - swellable material is one which becomes slippery on wetting.

10. A surgical device as claimed in any one of the preceding claims wherein the sleeve of water - swellable material is capable of swelling with sufficient force to dilate tissue surrounding the device when the device has been inserted into the human or animal body through a suitable orifice.

11. A surgical device as claimed in any one of the preceding claims wherein the internal diameter of the sleeve in its unswelled state is either the same as or slightly less than the external diameter of the tube, so that the dry sleeve may be fitted onto the tube by shrink fitting.

12. A surgical device as claimed in any one of the preceding claims wherein the water - swellable baterial is a polymeric material.

13. A surgical device as claimed in claim 12 wherein the polymeric material is a hydrophilic graft copolymer.

14. A surgical device as claimed in claim 13 wherein the graft copolymer is polyethylene graft copolymerised with acrylic acid.

15. A surgical device as claimed in claim 13 wherein the polymeric material is an ethylene vinyl acetate copolymer graft copolymerised with acrylic acid.

16. A surgical device as claimed in any one of claims 12 to 15 wherein the sleeve is coated with polyvinyl alcohol.

17. A surgical device comprising a tube of generally cylindrical shape and provided with an internal longitudinal channel and further provided with a plurality of holes extending from the internal channel to the outer surface of the tube, and further provided with a helical groove in the outer surface of the tube linking some if not all the holes.

18. A surgical device as claimed in any one of the preceding claims substantially as hereinbefore described with reference to the accompanying drawings.

19. A sterilised pack containing a surgical device as claimed in any one of the preceding claims.

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